

PATENT COOPERATION TREATY

PCT

INTERNATIONAL PRELIMINARY EXAMINATION REPORT (PCT Article 36 and Rule 70)

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| Applicant's or agent's file reference 1376 | FOR FURTHER ACTION | See Notification of Transmittal of International Preliminary Examination Report (Form PCT/PEA416) |
| International application No. PCT/JP 03/15956 | International filing date (day/month/year) 12.12.2003 | Priority date (day/month/year) 12.12.2002 |
| International Patent Classification (IPC) or both national classification and IPC C12Q1/68 | | |
| Applicant RIKEN et al. | | |

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|---|--|
| <p>1. This international preliminary examination report has been prepared by this International Preliminary Examining Authority and is transmitted to the applicant according to Article 36.</p> <p>2. This REPORT consists of a total of 6 sheets, including this cover sheet.</p> <p><input checked="" type="checkbox"/> This report is also accompanied by ANNEXES, i.e. sheets of the description, claims and/or drawings which have been amended and are the basis for this report and/or sheets containing rectifications made before this Authority (see Rule 70.16 and Section 607 of the Administrative Instructions under the PCT).</p> <p>These annexes consist of a total of 6 sheets.</p> | |
| <p>3. This report contains indications relating to the following items:</p> <ul style="list-style-type: none"> I <input checked="" type="checkbox"/> Basis of the opinion II <input type="checkbox"/> Priority III <input checked="" type="checkbox"/> Non-establishment of opinion with regard to novelty, inventive step and industrial applicability IV <input type="checkbox"/> Lack of unity of invention V <input checked="" type="checkbox"/> Reasoned statement under Rule 66.2(a)(ii) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement VI <input type="checkbox"/> Certain documents cited VII <input type="checkbox"/> Certain defects in the international application VIII <input type="checkbox"/> Certain observations on the international application | |

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| Date of submission of the demand 09.07.2004 | Date of completion of this report 25.02.2005 |
| Name and mailing address of the international preliminary examining authority:  European Patent Office D-80298 Munich Tel. +49 89 2399 - 0 Tx: 523656 epmu d Fax: +49 89 2399 - 4465 | Authorized Officer Schwachtgen, J-L Telephone No. +49 89 2399-8933 |



**INTERNATIONAL PRELIMINARY
EXAMINATION REPORT**

International application No. PCT/JP 03/15956

I. Basis of the report

1. With regard to the **elements** of the international application (*Replacement sheets which have been furnished to the receiving Office in response to an invitation under Article 14 are referred to in this report as "originally filed" and are not annexed to this report since they do not contain amendments (Rules 70.16 and 70.17)*):

Description, Pages

1-33, 35, 36, 40, 42, 44-47 as originally filed
34, 37-39, 41, 43 filed with telefax on 04.10.2004

Sequence listings part of the description, Pages

1-2 as originally filed

Claims, Numbers

1-78 as originally filed

Drawings, Sheets

1/12-12/12 as originally filed

2. With regard to the **language**, all the elements marked above were available or furnished to this Authority in the language in which the international application was filed, unless otherwise indicated under this item.

These elements were available or furnished to this Authority in the following language: , which is:

- the language of a translation furnished for the purposes of the international search (under Rule 23.1(b)).
- the language of publication of the international application (under Rule 48.3(b)).
- the language of a translation furnished for the purposes of international preliminary examination (under Rule 55.2 and/or 55.3).

3. With regard to any **nucleotide and/or amino acid sequence** disclosed in the international application, the international preliminary examination was carried out on the basis of the sequence listing:

- contained in the international application in written form.
- filed together with the international application in computer readable form.
- furnished subsequently to this Authority in written form.
- furnished subsequently to this Authority in computer readable form.
- The statement that the subsequently furnished written sequence listing does not go beyond the disclosure in the international application as filed has been furnished.
- The statement that the information recorded in computer readable form is identical to the written sequence listing has been furnished.

4. The amendments have resulted in the cancellation of:

- the description, pages:
- the claims, Nos.:

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the drawings, sheets:

5. This report has been established as if (some of) the amendments had not been made, since they have been considered to go beyond the disclosure as filed (Rule 70.2(c)).

(Any replacement sheet containing such amendments must be referred to under item 1 and annexed to this report.)

6. Additional observations, if necessary:

III. Non-establishment of opinion with regard to novelty, inventive step and industrial applicability

1. The questions whether the claimed invention appears to be novel, to involve an inventive step (to be non-obvious), or to be industrially applicable have not been examined in respect of:

the entire international application,

claims Nos. 76-78

because:

the said international application, or the said claims Nos. relate to the following subject matter which does not require an international preliminary examination (specify):

the description, claims or drawings (*indicate particular elements below*) or said claims Nos. are so unclear that no meaningful opinion could be formed (specify):

the claims, or said claims Nos. are so inadequately supported by the description that no meaningful opinion could be formed.

no international search report has been established for the said claims Nos. 76-78

2. A meaningful international preliminary examination cannot be carried out due to the failure of the nucleotide and/or amino acid sequence listing to comply with the standard provided for in Annex C of the Administrative Instructions:

the written form has not been furnished or does not comply with the Standard.

the computer readable form has not been furnished or does not comply with the Standard.

V. Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement

1. Statement

| | | |
|-------------------------------|-------------|-------------------------|
| Novelty (N) | Yes: Claims | 5-7, 21-24, 47 |
| | No: Claims | 1-4, 8-20, 25-46, 48-75 |
| Inventive step (IS) | Yes: Claims | |
| | No: Claims | 1-75 |
| Industrial applicability (IA) | Yes: Claims | 1-75 |
| | No: Claims | |

2. Citations and explanations

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see separate sheet

Re Item V

**Reasoned statement with regard to novelty, inventive step or industrial applicability;
citations and explanations supporting such statement**

Reference is made to the following documents:

D1: WO 02/31190 A (GENSET SA ;THILL GILBERT (FR)) 18 April 2002 (2002-04-18)

D2: KWON Y M ET AL: "Efficient amplification of multiple transposon-flanking sequences" JOURNAL OF MICROBIOLOGICAL METHODS, vol. 41, no. 3, August 2000 (2000-08), pages 195-199, XP002278628 ISSN: 0167-7012

1. The present application does not meet the criteria of Article 33(1) PCT, because the subject-matter of claims 1-4, 8-20, 25-46, 48-75 is not new in the sense of Article 33(2) PCT.

The document D1 discloses a method of isolating and analysing nucleic acid mismatch regions of e.g. mutant isoforms comprising 1) denaturing and re-hybridising isoforms 2) removing single-stranded regions other than internal single-stranded regions and 3) selecting heteroduplexes comprising at least one internal single-stranded region with a single stranded trap (claims 1-6). The 3' or 5' overhangs are removed during step 2) with exonuclease VII (page). A reduction (fragmentation) step is performed at the selection step 3) by cutting double stranded nucleic acids with restriction endonucleases (page 23, line 33 - page 34, line 13).

The disclosure in D1, thus anticipates all the technical features of the subject-matter of claims 1-4, 8-20, 25-46, 48-75.

3. Dependent claims 5-7, 21-24 and 47 do not contain any features which, in combination with the features of any claim to which they refer, meet the requirements of Article 33(3) PCT in respect of inventive step, see document D2, where restriction enzymes having a 4 bp recognition site and Y-shaped linkers have been used in a similar method (Figure 1).

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4. In his reply to the IPEA's Written Opinion, the Applicant has pointed out several alleged differences between the invention of the present application and the disclosure in D1. However, these differences are not reflected in the claims and are, thus, not taken into account for the establishment of the present report.